

REMARKS UNDER 37 CFR §1.111

Applicants acknowledge the current status of the claims as reported in the Office Action mailed 20 November 2003. Claims 4-12, 14-38, 44-46 and 61, are currently pending in this application and under consideration. Reconsideration and allowance of the application in light of the foregoing amendments and the following remarks are respectfully requested.

Independent claims 22, 29-31 and 36-38 are amended without prejudice as outlined below solely to advance the present application to allowance. Applicants reserve the right to prosecute the subject matter of the original claims in a later-filed continuation application, which properly claims the benefit of this application.

Specifically, independent claim 22, is amended to recite an isolated antibody, or antigen-binding portion thereof, comprising at least two variable regions, capable of binding an epitope of IL-18, wherein said isolated antibody, or antigen-binding portion thereof, is capable of binding human IL-18. This amendment is supported throughout the specification as filed, and particularly at page 11, line 28 to page 12, line 30. No new matter is added.

Independent claims 29 and 36 are amended to recite an isolated antibody, or antigen-binding portion thereof, comprising at least two variable regions,, at least one of said variable regions possessing the specific characteristics as recited in the respective claims, and, wherein said isolated antibody, or antigen-binding portion thereof, is capable of binding human IL-18. This amendment is supported throughout the specification as filed, and particularly at page 11, line 28 to page 12, line 30. No new matter is added.

Independent claims 30-31 and 37-38 are amended to recite an isolated antibody, or antigen-binding portion thereof, possessing the specific characteristics as recited in the respective claims, wherein said isolated human antibody, or said antigen-binding portion thereof is capable of binding human IL-18. This amendment is supported throughout the specification as filed, and no new matter is added.

In addition, independent claims 30, 31 and 38 are amended to recite antibody, or an antigen-binding portion thereof, "comprising" (as opposed to using the term "with" or "having") the recited regions, and the recited regions "having" (as opposed to using the term "comprising") specific sequences respectively, **SOLELY** to maintain term consistency within the claim set. It is well settled that claim transition terms "having", "with", and "comprising" are legally equivalent concerning claim interpretation and scope. Applicants assert these amendments: are supported by the application as filed; are obvious on their face; do not add new matter; do not alter the scope of the claimed subject matter; and are made for

reasons unrelated to patentability, but for the purpose of style, grammatical structure, and readability of the claims.

Reconsideration and allowance of the pending claims in light of the foregoing amendments and the following remarks are respectfully requested.

Claim rejections under 35 USC §112 first paragraph

In the Office Action, at page 2, paragraph 5, claims 22-38 are rejected under 35 USC §112, first paragraph, as containing subject matter not described in such a way as to convey to one skilled in the art that the Applicant was in possession of the claimed invention. Specifically, the Examiner asserts that claim 22 and claims dependent there from; claims 29-31; and claims 36-38 do not require that the antibodies formed from the subcomponents bind human IL-18; rather the only requirement is that the subcomponents come from an antibody that binds human IL-18. In addition, the Examiner asserts Applicants have not provided adequate support that the disclosed antibodies differ from the majority of antibodies and do not require all six CDRs in the context of an antibody framework. The Examiner has acknowledged that there are examples in the art in which the specificity of the antibody is determined by fewer than all six CDRs, but asserts that such antibodies are the exception.

Applicants disagree and traverse the rejection of the claims for reasons stated in the response filed on 21 April 2003.

As a preliminary matter claims 30-31 and claims 37-38 recite an isolated antibody, or an antigen binding portion thereof, comprising a light chain variable region and a heavy chain variable region. It is unclear why the Examiner has rejected claims 30-31, and claims 37-38, since the claimed antibody, or an antigen binding portion thereof, encompass six CDRs.

Notwithstanding Applicant's traverse, and without in any way acquiescing to the reasons for the present rejection, Applicants have amended independent claims 22, 29 and 36 to recite an isolated antibody or antigen-binding portion thereof comprising at least two variable regions. This amendment is supported throughout the specification as filed, and no new matter is added. Applicants assert that independent claims 22, 29 and 36 are amended without prejudice solely to advance the present application to allowance. Applicants reserve the right to prosecute the subject matter of the original claims in a later-filed continuation application, which properly claims the benefit of this application.

Finally, Applicants have amended claims 22, 29-31 and 36-38 to recite affirmatively that the claimed isolated antibody, or antigen-binding portion thereof, is capable of binding human IL-18. This amendment is supported throughout the specification as filed, and no new matter is added.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the rejection of claims 22-38 under 35 USC §112, first paragraph, is rendered moot. Applicants request the removal of the rejection of claims 22-38 under 35 USC §112, first paragraph .

In the Office Action, at page 3, paragraph 6, the Examiner has rejected claims 22-38 under 35 USC §112 first paragraph, because the specification, while enabling for antibodies and antigen binding fragments thereof in which 3 CDRs in the VH region and 3 CDRs in the VL region are defined, does not provide enablement for antibodies and antigen binding fragments thereof comprising less than three heavy chain and three light chain CDRs.

Once again, for reasons stated in the response filed on 21 April 2003, Applicants disagree and traverse the rejection of the claims.

Notwithstanding Applicant's traverse, and without in any way acquiescing to the reasons for the present rejection, in view of the claim amendments as described above, Applicants assert rejection of claims 22-38 under 35 USC §112 first paragraph is rendered moot. Applicants respectfully request the removal of the rejection of claims 22-38 under 35 USC §112 first paragraph.

Claim rejections under 35 USC §103(a)

In the Office Action, at page 5, paragraph 8, claims 4-12, 14-24, 44-46 and 61 are rejected under 35 USC §103(a) as being unpatentable over Kucherlapati et al., (US Patent No. 6,075,181) and Dinarello et al., (J. Leukoc. Biol. 1998; 63:658-664). Specifically, the Examiner asserts "that the combination of Dinarello et al. and Kucherlapati et al. provide both the motivation to produce human antibodies to human IL-18 and a reasonable expectation of successfully producing human antibodies to human IL-18 ". Applicants respectfully disagree.

To establish a *prima facie* case of obviousness, three criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all claim limitations (MPEP §2143). Hindsight reconstruction of a claimed invention, absent a teaching or suggestion in the art is impermissible (MPEP §2142). In addition, there exists a requirement for an evidentiary showing of the teaching or motivation to combine prior art references. Regardless of the basis for motivation (i.e., prior art references themselves, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved), case law affirms "the requirement for actual evidence. That is, the showing must be clear and particular. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence'." (*In Re Dembiczak*, 175 F.3d 994,1000 Fed. Cir. 1999).

Applicant's invention is directed to human antibodies or antigen binding portions thereof capable of binding human IL-18.

The Examiner asserts Kucherlapati et al. disclose a method of generating fully human antibodies to antigens. In the Office action, at page 5, the Examiner acknowledges:

***"Kucherlapati et al. do not teach human antibodies to human IL-18.*"**

The Examiner asserts Dinarello et al. disclose recombinant human IL-18, and a clinical need for inhibiting IL-18 activity, potentially via an anti-IL-18 antibody. In the Office action, at page 6, the Examiner acknowledges:

***"-- the failure of Dinarello et al. to teach human antibodies--.*"**

BY THE EXAMINER'S OWN ADMISSION, THE CITED REFERENCES, NEITHER SINGULARLY OR IN COMBINATION, TEACH, SUGGEST, OR MOTIVATE ONE SKILLED IN THE ART TO PRODUCE A HUMAN ANTIBODY CAPABLE OF NEUTRALIZING THE ACTIVITY OF HUMAN IL-18.

In addition, Applicants assert that the Examiner has failed to provide any actual evidentiary motivation to combine the cited reference (other than that of the present disclosure as filed) as required by law.

In *Dembiczak*, the invention at issue was a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern. Claim to the trash bag design was rejected as obvious in view of the cited art, which included:

- A holiday art handbook disclosing a "Crepe Paper Jack-O-Lantern" comprising orange crepe paper, construction paper cut-outs in the shape of facial features, and wadded newspaper as filling;
- A teacher's book disclosing a "paper bag pumpkin" made by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint;
- A US patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; and
- Prior art "conventional" plastic lawn or trash bags.

The Board of Patent Appeals and Interferences (the Board) affirmed the obviousness rejection based on the combination of the references, stating that the references would have suggested the application of facial indicia to the prior art plastic trash bags.

On further review before the United States Court of Appeals For The Federal Circuit, the Court noted that the Board, rather than pointing to specific information in the references suggesting their combination, described, in detail, the similarities between the references and the claimed invention, noting that one reference or the other--in combination with each other and the conventional trash bags--described all of the elements of the pending claims. The Court found that nowhere did the Board

particularly identify any suggestion, teaching, or motivation to combine the references. The Court ultimately reversed the obviousness rejection "Because there is no evidence in the record of a suggestion, teaching, or motivation to combine the prior art references asserted against the pending claims. (*Id.* at 1003). A photocopy of the *Dembiczak* opinion, which is the current state of the law concerning suggestion or motivation to combine references to establish obviousness, is provided herewith for the Examiner's review and consideration.

In the present rejection to Applicants' claimed invention, the Examiner maintains that one of ordinary skill is suggested or motivated to combine the cited references. The Examiner asserts:

"the ordinary artisan at the time the invention was made would have been motivated to produce fully human monoclonal antibodies that could bind to and neutralize human IL-18 in order to provide a therapeutic reagent that could be administered to humans without eliciting the undesirable immune responses associated with the administration of rodent or even humanized rodent antibodies, as taught by Kucherlapati et al. The desirability of neutralizing antibodies to human IL-18 is clearly taught by Dinarllo et al".

The Examiner alleges that, at the time the invention was made, one of ordinary skill in the art would have "had reasonable expectation that, given the availability of recombinant human IL-18, fully human antibodies to human IL-18 could be produced using the method of Kucherlapati et al."

Applicants respectfully disagree. Neither Kucherlapati nor Dinarello et al., singularly or in combination, teach or suggest making human antibodies to human IL-18. Even assuming, *in arguendo*, that the cited reference can be properly combined, the Examiner's argument is, at best, "obvious-to-try" reasoning, which, also, is improper to establish or to sustain a case of *prima facie* obviousness.

Applicants assert that, in view of the clinical importance of IL-18, neither reference teach or suggest a fully human anti-IL-18 monoclonal antibody which is actual evidence (by its absence) that such an approach was novel, unobvious, and even unobvious-to-try (even to the principal investigators of the cited art, much less a person of ordinary skill in the art) at the time of filing the present invention.

Applicants assert that the Examiner fails to provide the requisite "*clear and particular showing*" of any suggestion or motivation to combine the cited references; that, like the Board in *Dembiczak*, the Examiner has combined the cited references one-by-one, and element-by-element without demonstrating how and where the references teach, suggest, or motivate that they should be or could be combined to arrive at Applicants' invention.

Applicants teach how to make and use human antibodies to human IL-18. Neither the teachings of the cited references, nor the assertions of the Examiner, render Applicants' claimed invention obvious in the absence of Applicants' enabling disclosure. A disclosure of fully human monoclonal antibodies combined with a reference disclosing neutralizing anti-IL-18 antibodies is NOT a clear and particular

teaching, suggestion, or motivation to one of skill in the art to make the human anti- IL-18 antibody of the present invention.

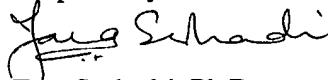
Patchwork compilation of art is not sufficient (and is, in fact, improper) to establish a *prima facie* case of obviousness. Combination of this art using hindsight reconstruction is impermissible. Indeed, because of the Examiner's expertise and state-of-the-art knowledge in the biotechnology field of the present invention, actual evidentiary showing is "especially important" due to the fact that "the very ease with which the invention can be understood may prompt one '*to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.*'" (*In Re Dembicza*k, at 999).

Applicants maintain that in the absence of any clear and particular evidentiary showing of teaching, suggestion, or motivation to combine the cited references establishment of a *prima facie* case of obviousness fails, and rejection of Applicants' invention as claimed is improper. In view of the foregoing remarks, Applicants respectfully request the withdrawal of the rejection to claims 4-12, 14-24, 44-46 and 61 under 35 USC § 103(a).

Conclusion

In view of the foregoing amendments and remarks, Applicants believe the rejections set forth in the Office Action dated 20 November 2003 have been avoided or overcome and consequently their application is in condition for allowance. Applicants, therefore, respectfully request reconsideration and removal of the rejections, and allowance of the pending claims as amended.

Respectfully submitted,



Tara Seshadri, Ph.D.
Registration No. 48,591
Agent for Applicants
Abbott Bioresearch Center, Inc.
100 Research Drive
Worcester, MA 01605
(508) 688-8058



LEXSEE 175 F.3D 994

IN RE ANITA DEMBICZAK and BENSON ZINBARG, Appellants.

98-1498

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

175 F.3d 994; 1999 U.S. App. LEXIS 8109; 50 U.S.P.Q.2D (BNA) 1614

April 28, 1999, Decided

PRIOR HISTORY: [**1]Appealed from: Patent and Trademark Office Board of Patent Appeals and Interferences. (Serial No. 08/427,732).

DISPOSITION: REVERSED.

LexisNexis (TM) HEADNOTES - Core Concepts:

COUNSEL: David P. Gordon, of Stamford, Connecticut, argued for appellant. Of counsel was Thomas A. Gallagher, of Stamford, Connecticut.

John M. Whealan, Associate Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With him on the brief were Albin F. Drost, Acting Solicitor, and David R. Nicholson, Associate Solicitor.

JUDGES: Before MAYER, Chief Judge, MICHEL and CLEVENGER, Circuit Judges.

OPINIONBY: CLEVENGER

OPINION: [*996] CLEVENGER, Circuit Judge.

Anita Dembiczak and Benson Zinbarg appeal the rejection, upheld by the Board of Patent Appeals and Interferences, of all pending claims in their Application No. 08/427,732. See *Ex Parte Dembiczak*, No. 96-2648, slip op. at 43 (May 14, 1998). Because the Board erred in sustaining rejections of the pending claims as obvious under 35 U.S.C. § 103(a) (Supp. 1998), and for obviousness-type double patenting, we reverse.

I

The invention at issue in this case is, generally speaking, a large trash bag made of orange plastic and decorated with lines and facial features, allowing the

bag, when filled [**2] with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern. As the inventors, Anita Dembiczak and Benson Zinbarg (collectively, "Dembiczak") note, the invention solves the long-standing problem of unsightly trash bags placed on the curbs of America, and, by fortuitous happenstance, allows users to express their whimsical or festive nature while properly storing garbage, leaves, or other household debris awaiting collection. Embodiments of the invention--sold under a variety of names, including Giant Stuff-A-Pumpkin TM, Funkins, Jack Sak TM, and Bag-O-Fun TM--have undisputedly been well-received by consumers, who bought more than seven million units in 1990 alone. Indeed, in 1990, the popularity of the pumpkin bags engendered a rash of thefts around Houston, Texas, leading some owners to resort to preventative measures, such as greasing the bags with petroleum jelly and tying them to trees. See R. Piller, "Halloween Hopes Die on the Vine," *Hous. Chron.*, Oct. 19, 1990, at 13A.

The road to profits has proved much easier than the path to patentability, however. In July 1989, Dembiczak filed a utility patent application generally directed to the pumpkin bags. [**3] In a February 1992 appeal, the Board of Patent Appeals and Interferences ("the Board") reversed the Examiner's rejection, but entered new grounds for rejection. Dembiczak elected to continue prosecution, filing a continuation application to address the new grounds for rejection. Thereafter, the invention made a second appearance before the Board, in April 1993, when the Board both sustained the Examiner's rejection and again entered new grounds for rejection. Again, a continuation application was filed (the instant application). And again the Examiner's rejection was appealed to the Board, which sustained the rejection in a May 14, 1998, decision. See *Dembiczak*, slip op. at 43.

175 F.3d 994, *; 1999 U.S. App. LEXIS 8109, **;
50 U.S.P.Q.2D (BNA) 1614

A

The patent application at issue includes claims directed to various embodiments of [*997] the pumpkin bag. Claims 37, 49, 51, 52, 58 through 64, 66 through 69, and 72 through 81 are at issue in this appeal. Though the claims vary, independent claim 74 is perhaps most representative:

74. A decorative bag for use by a user with trash filling material, the bag simulating the general outer appearance of an outer surface of a pumpkin having facial indicia thereon, comprising:

a flexible waterproof plastic [**4] trash or leaf bag having

an outer surface which is premanufactured orange in color for the user to simulate the general appearance of the outer skin of a pumpkin, and having

facial indicia including at least two of an eye, a nose and a mouth on the orange color outer surface for forming a face pattern on said orange color outer surface to simulate the general outer appearance of a decorative pumpkin with a face thereon,

said trash or leaf bag having first and second opposite ends, at least said second end having an opening extending substantially across the full width of said trash or leaf bag for receiving the trash filling material,

wherein when said trash or leaf bag is filled with trash filling material and closed, said trash or leaf bag takes the form and general appearance of a pumpkin with a face thereon.

All of the independent claims on appeal, namely 37, 52, 72, and 74, contain limitations that the bag must be "premanufactured orange in color," have "facial indicia," have openings suitable for filling with trash material, and that when filled, the bag must have a generally rounded appearance, like a pumpkin. Independent claims 37, 52, and 72 add the [**5] limitation that the bag's height must at least 36 inches. Claim 72 requires that the bag be made of a "weatherproof material," and claim 74, as shown above, requires that the bag be "waterproof." Claim 52 recites a "method of assembling" a bag with the general characteristics of apparatus claim 37.

B

The prior art cited by the Board includes:

- (1) pages 24-25 of a book entitled "A Handbook for Teachers of Elementary Art," by Holiday Art Activities ("Holiday"), describing how to teach children to make a "Crepe Paper Jack-O-Lantern" out of a strip of orange crepe paper, construction paper cut-outs in the shape of facial features, and "wadded newspapers" as filling;
- (2) page 73 of a book entitled "The Everything Book for Teachers of Young Children," by Martha Shapiro and Valerie Indenbaum ("Shapiro"), describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint;
- (3) U.S. Patent No. 3,349,991 to Leonard Kessler, entitled "Flexible Container" ("Kessler"), describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material;
- (4) [**6] U.S. Patent No. Des. 310,023, issued August 21, 1990 to Dembiczak ("Dembiczak '023"), a design patent depicting a bag with a jack-o'-lantern face;
- (5) U.S. Patent No. Des. 317,254, issued June 4, 1991 to Dembiczak ("Dembiczak '254"), a design patent depicting a bag with a jack-o'-lantern face; and,
- (6) Prior art "conventional" plastic lawn or trash bags ("the conventional trash bags").

Using this art, the Board affirmed the Examiner's final rejection of all the independent claims (37, 52, 72, 74) under 35 U.S.C. § 103, [*998] holding that they would have been obvious in light of the conventional trash bags in view of the Holiday and Shapiro references. The Board determined that, in its view of the prior art, "the only difference between the invention presently defined in the independent claims on appeal and the orange plastic trash bags of the prior art and the use of such bags resides in the application of the facial indicia to the outer

175 F.3d 994, *; 1999 U.S. App. LEXIS 8109, **;
50 U.S.P.Q.2D (BNA) 1614

surface of the bag." Dembiczak, slip op. at 18. The Board further held that the missing facial indicia elements were provided by the Holiday and Shapiro references' description of painting jack-o'-lantern faces on paper bags. See [**7] id. at 18-19. Dependent claims 49 and 79, which include a "gussets" limitation, were considered obvious under similar reasoning, except that the references cited against them included Kessler. See id. at 7.

The Board also affirmed the Examiner's obviousness-type double patenting rejection of all the independent claims in light of the two Dembiczak design patents ('023 and '254) and Holiday. See id. at 12. The Board held that the design patents depict a generally rounded bag with jack-o'-lantern facial indicia, and that the Holiday reference supplies the missing limitations, such as the "thin, flexible material" of manufacture, the orange color, the initially-open upper end, and the trash filling material. The Board also stated that the various limitations of the dependent claims--e.g., color, the inclusion of leaves as stuffing, and the dimensions--would all be obvious variations of the depictions in the Dembiczak design patents. See id. at 8-9. In addition, using a two-way test for obviousness-type double patenting, the Board held that the claims of the Dembiczak design patents "do not exclude" the additional structural limitations of the pending utility claims, [**8] and thus the design patents were merely obvious variations of the subject matter disclosed in the utility claims. See id. at 11. The Board further upheld, on similar grounds and with the inclusion of the Kessler reference, the obviousness-type double patenting rejection of dependent claim 49. See id. at 12.

This appeal followed, vesting this court with jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994).

II

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); see *Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 U.S.P.Q. (BNA) 459, 465, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. See *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. (BNA) [**9] at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 U.S.P.Q.2D (BNA)

1123, 1128 (Fed. Cir. 1993). We therefore review the ultimate determination of obviousness without deference to the Board, while examining any factual findings for clear error. See, e.g., *In re Zurko*, 142 F.3d 1447, 1459, 46 U.S.P.Q.2D (BNA) 1691, 1700 (Fed. Cir.) (en banc), cert. granted, 119 S. Ct. 401 (1998).

A

Our analysis begins in the text of section 103 quoted above, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the "tempting but forbidden zone of hindsight," see *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873, 228 U.S.P.Q. (BNA) 90, 98 (Fed. Cir. 1985), overruled on other grounds by *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 U.S.P.Q.2D (BNA) 1097 [*999] (Fed. Cir. 1998), when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted [**10] wisdom in the field. See, e.g., *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. (BNA) 303, 313 (Fed. Cir. 1983). Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." Id.

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select [**11] the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins &*

175 F.3d 994, *; 1999 U.S. App. LEXIS 8109, **;
50 U.S.P.Q.2D (BNA) 1614

Refractories, Inc., 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) ("The invention [**12] must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board fell into the hindsight trap.

We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 U.S.P.Q.2D (BNA) 1626, 1630 (Fed. Cir. 1996), *Para-Ordnance Mfg. v. SGS Imports Intern., Inc.*, 73 F.3d 1085, 1088, 37 U.S.P.Q.2D (BNA) 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," *Rouffet*, 149 F.3d at 1355, 47 U.S.P.Q.2D (BNA) at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C.R. Bard*, 157 F.3d 1340 at 1352, 48 U.S.P.Q.2D (BNA) at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." E.g., *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 U.S.P.Q.2D (BNA) [**13] 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of [*1000] material fact."); *In re Sichert*, 566 F.2d 1154, 1164, 196 U.S.P.Q. (BNA) 209, 217 (CCPA 1977) ("The examiner's conclusory statement that the specification does not teach the best mode of using the invention is unaccompanied by evidence or reasoning and is entirely inadequate to support the rejection."). In addition to demonstrating the propriety of an obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the factual disputes, if any, between the applicant and the Board; and (3) facilitation of review on appeal. Here, however, the Board did not make particular findings

regarding the locus of the suggestion, teaching, or motivation to combine the prior art references.

All the obviousness rejections affirmed by the Board resulted from a combination of prior art references, e.g., the conventional trash or yard bags, and the Holiday and Shapiro publications teaching [**14] the construction of decorated paper bags. See Dembicza, slip op. at 6-7. To justify this combination, the Board simply stated that "the Holiday and Shapiro references would have suggested the application of . . . facial indicia to the prior art plastic trash bags." Id. at 18-19. However, rather than pointing to specific information in Holiday or Shapiro that suggest the combination with the conventional bags, the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other-in combination with each other and the conventional trash bags--described all of the limitations of the pending claims. See id. at 18-28. Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the children's art references (Holiday and Shapiro) with the conventional trash or lawn bag references, nor does the Board make specific--or even inferential--findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness [**15] analysis. See, e.g., *Pro-Mold & Tool*, 75 F.3d at 1573, 37 U.S.P.Q.2D (BNA) at 1630.

To the contrary, the obviousness analysis in the Board's decision is limited to a discussion of the ways that the multiple prior art references can be combined to read on the claimed invention. For example, the Board finds that the Holiday bag reference depicts a "premanufactured orange" bag material, see Dembicza, slip op. at 21, finds that Shapiro teaches the use of paper bags in various sizes, including "large", see id. at 22-23, and concludes that the substitution of orange plastic for the crepe paper of Holiday and the paper bags of Shapiro would be an obvious design choice, see id. at 24. Yet this reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the Holiday and Shapiro references teach or suggest their combination with the conventional trash or lawn bags to yield the claimed invention. See *Rouffet*, 149 F.3d at 1357, 47 U.S.P.Q.2D (BNA) at 1459 (noting Board's failure to explain, when analyzing the prior art, "what specific understanding or technical principle . . . would have suggested the combination"). Because we do not discern any finding by [**16] the Board that there was a suggestion, teaching, or motivation to combine the prior art references cited against the pending claims, the Board's conclusion of obviousness, as a matter of law, cannot stand. See *C.R. Bard*, 157 F.3d at 1352, 48 U.S.P.Q.2D (BNA) at 1232;

175 F.3d 994, *; 1999 U.S. App. LEXIS 8109, **;
50 U.S.P.Q.2D (BNA) 1614

Rouffet, 149 F.3d at 1359, 47 U.S.P.Q.2D (BNA) at 1459; *Fritch*, 972 F.2d at 1265, 23 U.S.P.Q.2D (BNA) at 1783; *Fine*, 837 F.2d at 1075, 5 U.S.P.Q.2D (BNA) at 1600; *Ashland Oil*, 776 F.2d at 297, 227 U.S.P.Q. (BNA) at 667.

B

The Commissioner of Patents and Trademarks ("Commissioner") attempts to justify the Board's decision on grounds [*1001] different from that relied upon by the Board, arguing that one of ordinary skill in the art would have been motivated to combine the references. Of course, in order to do so, the Commissioner must do what the Board did not do below: make specific findings of fact regarding the level of skill in the art ("a designer and manufacturer of trash and leaf bags, particularly one specializing in the ornamental and graphic design of such bags"), Resp't Br. at 14, the relationship between the fields of conventional trash bags and children's crafts, respectively ("the artisan would also have been well aware of the ancillary, [*17] corollary, and atypical uses of 'trash' bags such as their application in hobby and art projects"), Resp't Br. at 15, and the particular features of the prior art references that would motivate one of ordinary skill in a particular art to select elements disclosed in references from a wholly different field ("a designer and manufacturer of trash and leaf bags would have recognized the paper bag in Shapiro to be a trash bag and therefore would have been motivated to combine it with the admitted prior art plastic trash and leaf bags to arrive at the claimed invention"), Resp't Br. at 15. The Commissioner also appears to cite additional references in support of his obviousness analysis, noting that at least two design patents (in the record but not cited against the presently pending claims) teach the placement of "graphical information, including text, designs, and even facial indicia, to colored bags." Resp't Br. at 16. This new analysis, apparently cut from whole cloth in view of appeal, does little more than highlight the shortcomings of the decision below, and we decline to consider it. See, e.g., *In re Robertson*, 1999 U.S. App. LEXIS 3224, 169 F.3d 743, 746, [*18] 49 U.S.P.Q.2D (BNA) 1949, 1951 (Fed. Cir. 1999) ("We decline to consider [the Commissioner's] newly-minted theory as an alternative ground for upholding the agency's decision."); *In re Soni*, 54 F.3d 746, 751, 34 U.S.P.Q.2D (BNA) 1684, 1688 (Fed. Cir. 1995); *In re Hounsfieeld*, 699 F.2d 1320, 1324, 216 U.S.P.Q. (BNA) 1045, 1049 (Fed. Cir. 1983) (rejecting an "attempt[] by the Commissioner 'to apply a new rationale to support the rejection.'"); see also 35 U.S.C. § 144 (1994) (an appeal to the Federal Circuit "is taken on the record before The Patent and Trademark Office"). Because the Board has not established a prima facie case of obviousness, see *In re Bell*, 991 F.2d 781,

783, 26 U.S.P.Q.2D (BNA) 1529, 1531 (Fed. Cir. 1993) ("The PTO bears the burden of establishing a case of *prima facie obviousness*."), we therefore reverse the obviousness rejections, and have no need to address the parties' arguments with respect to secondary factors.

III

Dembiczak also asks this court to reverse the Board's rejection of the pending claims for obviousness-type double patenting, which is a judicially-created doctrine that seeks to prevent the applicant from expanding the grant of the patent right beyond the [*19] limits prescribed in Title 35. See, e.g., *In re Braat*, 937 F.2d 589, 592, 19 U.S.P.Q.2D (BNA) 1289, 1291-92 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 892, 225 U.S.P.Q. (BNA) 645, 648 (Fed. Cir. 1985). See also 35 U.S.C. § 154(a)(2) (Supp. 1998) (discussing patent term). The doctrine prohibits claims in a second patent which define "merely an obvious variation" of an invention claimed by the same inventor in an earlier patent. *Braat*, 937 F.2d at 592, 19 U.S.P.Q.2D (BNA) at 1292 (quoting *In re Vogel*, 57 C.C.P.A. 920, 422 F.2d 438, 441, 164 U.S.P.Q. (BNA) 619, 622 (CCPA 1970)). Thus, unless a claim sought in the later patent is patentably distinct from the claims in an earlier patent, the claim must be rejected. See *In re Goodman*, 11 F.3d 1046, 1052, 29 U.S.P.Q.2D (BNA) 2010, 2015 (Fed. Cir. 1993); *Vogel*, 422 F.2d at 441, 164 U.S.P.Q. (BNA) at 622. This question is one of law, which we review de novo. See *Goodman*, 11 F.3d at 1052, 29 U.S.P.Q.2D (BNA) at 2015; *Texas Instruments Inc. v. United States Int'l Trade Comm'n*, 988 F.2d 1165, 1179, 26 U.S.P.Q.2D (BNA) 1018, 1029 (Fed. Cir. 1993).

[*1002] A

The law provides that, in some very rare cases, obvious-type double patenting may be found between design and utility patents. [*20] See *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 939-40, 220 U.S.P.Q. (BNA) 481, 487 (Fed. Cir. 1983) (noting that, while theoretically possible, "double patenting is rare in the context of utility versus design patents"); *In re Thorington*, 57 C.C.P.A. 759, 418 F.2d 528, 536-37, 163 U.S.P.Q. (BNA) 644, 650 (CCPA 1969) (Double patenting between a design and utility patent is possible "if the features producing the novel aesthetic effect of a design patent or application are the same as those recited in the claims of a utility patent or application as producing a novel structure."); *In re Phelan*, 40 C.C.P.A. 1023, 205 F.2d 183, 98 U.S.P.Q. (BNA) 156 (CCPA 1953); *In re Barber*, 23 C.C.P.A. 834, 81 F.2d 231, 28 U.S.P.Q. (BNA) 187 (CCPA 1936); *In re Hargraves*, 19 C.C.P.A. 784, 53 F.2d 900, 11 U.S.P.Q. (BNA) 240 (CCPA 1931). In these cases, a "two-way" test is applicable. See *Carman*, 724 F.2d at 940, 220 U.S.P.Q.

175 F.3d 994, *; 1999 U.S. App. LEXIS 8109, **;
50 U.S.P.Q.2D (BNA) 1614

(BNA) at 487. Under this test, the obviousness-type double patenting rejection is appropriate only if the claims of the two patents cross-read, meaning that "the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the [**21] other patent, and vice versa." *Id.*, 220 U.S.P.Q. (BNA) at 487. See also *Braat*, 937 F.2d at 593, 19 U.S.P.Q.2D (BNA) at 1292 (explaining two-way test).

B

In making its double patenting rejection, the Board concluded that all but one of the pending claims of Dembiczak's utility application would have been merely an obvious variation of the claims of the earlier-issued design patents--the Dembiczak '023 and '254 references--in light of the Holiday reference. The remaining claim, dependent claim 49, was judged obvious in light of the combination of the Dembiczak design patents, Holiday, and the Kessler reference.

Acknowledging that the two-way test was required by *Carman*, 724 F.2d at 940, 220 U.S.P.Q. (BNA) at 487, the Board concluded that "the design claimed in each of appellants' design patents does not exclude the features pertaining to the construction and color of the bag, the use of a plastic material for making the bag, the size or thickness of the bag . . . or the use of various types of filling material The particular details of the facial indicia would have been a matter of design choice as evidenced by the Holiday handbook," and that therefore, in view of Holiday, the claims of the [**22] design patents were obvious variants of the pending utility patent claims. See Dembiczak, slip op. at 11. We disagree. In order for a design to be unpatentable because of obviousness, there must first be a basic design reference in the prior art, the design characteristics of which are "basically the same as the claimed design." *In re Borden*, 90 F.3d 1570, 1574, 39 U.S.P.Q.2D (BNA) 1524, 1526 (Fed. Cir. 1996); *In re Rosen*, 673 F.2d 388, 391, 213 U.S.P.Q. (BNA) 347, 350 (CCPA 1982). The phrase "having facial indicia thereon" found in the claims of the pending utility application is not a design reference that is "basically the same as the claimed design." *Borden*, 90 F.3d at 1574, 39 U.S.P.Q.2D (BNA) at 1526. In fact, it describes precious little with respect to design characteristics. The Board's suggestion that the design details were simply "a matter of design choice" evinces a misapprehension of the subject matter of

design patents. E.g., *Carman*, 724 F.2d at 939 n.13, 220 U.S.P.Q. (BNA) at 486 n.13 ("Utility patents afford protection for the mechanical structure and function of an invention whereas design patent protection concerns the ornamental or aesthetic features of a design.") Indeed, we note [**23] that the two design patents at issue here--the Dembiczak '023 and '254 patents--were considered nonobvious over each other, and were even the subject of a restriction requirement. See 35 U.S.C. § 121 (1994) ("If two or more independent and distinct inventions are claimed in one [*1003] application, the Commissioner may require the application to be restricted to one of the inventions."); 37 C.F.R. § 1.142. The position adopted by the Board--that a textual description of facial indicia found in the claims of the utility patent application makes obvious the specific designs claimed in the (patently distinct) Dembiczak design patents--would presumably render obvious, or even anticipate, all design patents where a face was depicted on a bag. But this, of course, is not the law; the textual description cannot be said to be a reference "basically the same as the claimed design," of the design patents at issue here. *Borden*, 90 F.3d at 1574, 39 U.S.P.Q.2D (BNA) at 1526 (internal quotation marks omitted). The Board's conclusion of obviousness is incorrect.

Because we find that the Board erred in concluding that the design patents were obvious variants of the pending utility claims, we need not address [**24] the other prong of the two-way double patenting test--whether the pending utility claims are obvious variations of the subject matter claimed in the design patents. See *Carman*, 724 F.2d at 939, 220 U.S.P.Q. (BNA) at 487 (both prongs of the two-way test required for obviousness-type double patenting). The double patenting rejections are reversed.

IV

Because there is no evidence in the record of a suggestion, teaching, or motivation to combine the prior art references asserted against the pending claims, the obviousness rejections are reversed. In addition, because the Board misapprehended the test for obviousness-type double patenting, and because the pending utility claims do not render obvious the design patents, the double patenting rejections are also reversed.

REVERSED